AR201-13924

Please respond to wjones@pinechemicals.org

To: NCIC OPPT/DC/USEPA/US@EPA, ChemRTK HPV/DC/USEPA/US@EPA, Rtk Chem/DC/USEPA/US@EPA

cc:

Subject: RESPONSE TO COMMENTS - PINE CHEMICALS ASSOCIATION

Please find attached the Pine Chemicals Association HPV Task Forces' response to EPA and PCRM comments concerning our Test Plan for Rosin Adducts and Adduct Salts.

Walter L. Jones, President & COO

Pine Chemicals Association, Inc.

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- Response to comments.pdf

August 29, 2002

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116

Attention: Chemical Right-to-Know Program

Re: Response to Comments and Amendments to Pine Chemicals Association, Inc. Test Plan for Rosin Adducts and Adduct Salts

Dear Ms. Whitman:

The Pine Chemicals Association, Inc. (PCA) HPV Task Force is pleased to submit its response to comments received on its September 2001 Test Plan for Rosin Adducts and Adduct Salts. We have carefully reviewed the comments submitted by the Environmental Protection Agency (EPA) and the Physicians Committee for Responsible Medicine (PCRM) in March 2002. This document responds to those comments and amends our September 2001 Test Plan. We have organized the submission by subject matter in the same order as our Test Plan.

RESPONSE TO COMMENTS & AMENDMENTS TO TEST PLAN

Categorization of Substances / Selection of Test Material

In its Test Plan for Rosin Adducts and Adduct Salts, PCA proposed to group six substances and to test fumarated rosin (CAS # 65997-04-8) to represent the category based on several factors, including 1) all the substances in the category are structurally similar since they are either fumarated or maleated adducts of rosin or rosin salts; and 2) the fumarated rosin is the most chemically and thermodynamically stable adduct. Although EPA believes the grouping was generally well supported, the Agency questioned the justification of fumarated rosin as the representative compound for this category. On the other hand, PCRM[1] recommended that PCA combine the rosin adducts and adduct salts with its Test Plan for Rosins and Rosin Salts and conduct no further health effects or aquatic toxicity testing on rosins or rosin adducts.

[1] PCRM's comments were also submitted on behalf of People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute.

EPA is concerned that maleated rosin might be more biologically active than fumarated rosin -- the representative test substance. However, it should be noted that at the temperature where rosin/fumaric acid adduction occurs, isomerization and dehydration of a fraction of the fumaric acid to maleic anhydride invariably takes place. This results in a portion of the adduct being rosin/maleic anhydride as demonstrated on the gas chromatogram below (see Fig. 1). The chromatogram clearly shows that approximately 10-20% of the test substance is the rosin/maleic anhydride reaction product. Therefore, any potential effects of the maleic anhydride adduct will be included in the testing of the fumaric acid adduct. Furthermore, testing the fumaric acid adduct will be equivalent to testing the maleic anhydride adduct because we expect that the anhydride adduct will be readily hydrolyzed to the maleic acid adduct in an aqueous media. Since the maleic acid adduct and the fumaric acid adduct are cis-trans isomers, the hypothetical reactivity of the two adducts to proteins or other macromolecules should be equivalent. After carefully considering the EPA and PCRM comments, PCA believes that the category should remain as originally proposed. Nonetheless, PCA will undertake an additional acute test (OECD 425, the up-down procedure) on maleated rosin (CAS # 68425-08-1) in order to demonstrate that the testing on fumarated rosin represents maleated rosin.

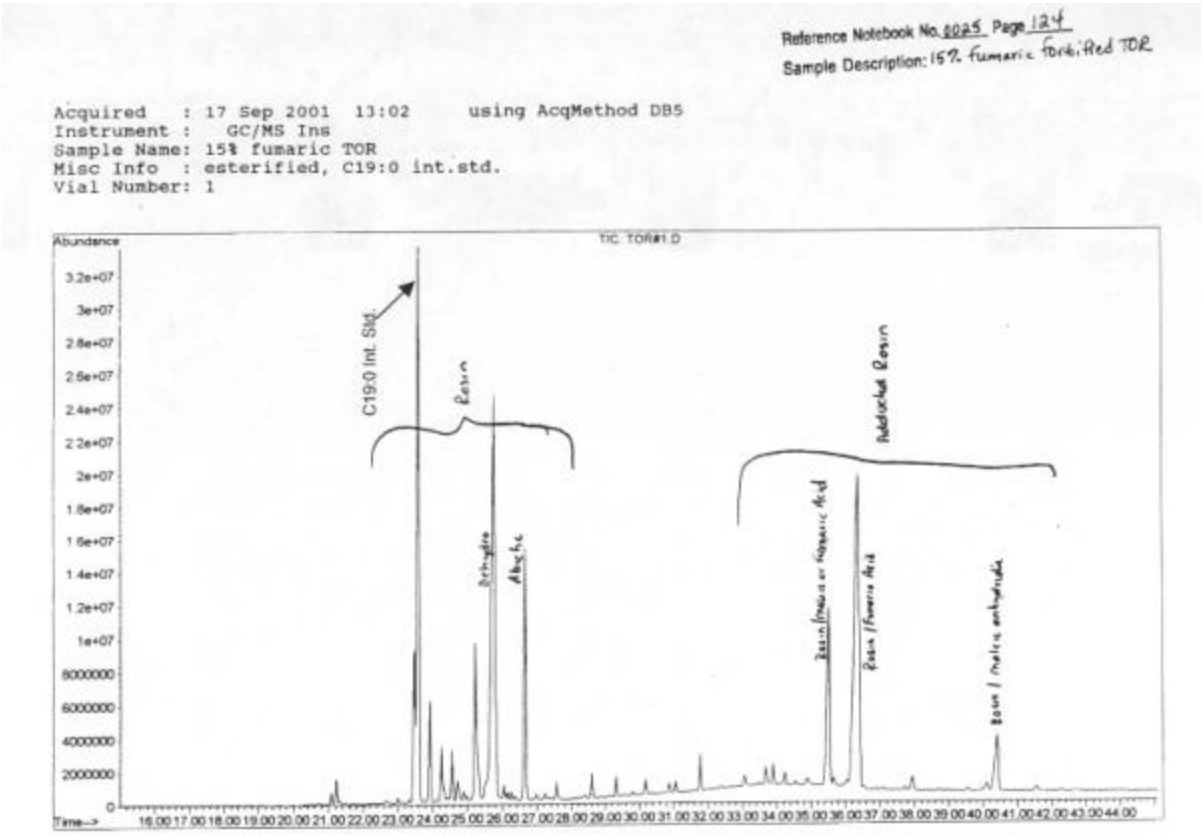

Figure 1. Chromatogram of 15% fumaric fortified tall oil rosin (TOR)

EPA also requested that PCA provide information on the range of adduct to rosin ratios for commercially available products and for the substance to be tested. Their concern was that variations in the ratios of rosin adducts to rosin in the product might have an effect on physicochemical properties, as well as ecotoxicity and health effects. PCA notes that the range of adduct to rosin varies widely depending on the intended end use of the final product. For example, the level of adduct in a rosin based ink resin can vary from about 1 to 15%. Rosin based paper sizes are generally in the range of 3 to 5%. The particular sample of fumarated rosin selected as the test substance is a material having about 15% adduct to ensure that testing was conducted on a typical product, high in adduct and relatively low in rosin (which is addressed in a separate test plan).

Physicochemical and Environmental Fate

EPA agreed that PCA's approach to physicochemical and environmental fate data was "acceptable for purposes of the HPV Challenge Program." Nonetheless, because PCA stated that maleated rosin adduct would hydrolyze by addition into the acid form, EPA requested hydrolysis data on the maleated rosin adduct. After consideration of EPA's suggestion, PCA will conduct a hydrolysis test (OECD 111) on the maleated rosin adduct.

Ecotoxicity Tests

EPA agreed with the proposed acute toxicity testing of fish, daphnia and algae, but suggested that PCA provide more information on the method as it relates to maximizing solubility, as well as consider conducting a chronic daphnid reproduction test. In contrast, PCRM recommended that PCA forego fish testing in favor of using models like ECOSAR or TETRATOX. However, neither of these models has been recognized as part of the SIDS or HPV program.

After consideration of these comments, PCA does not intend to amend its Test Plan with regard to the proposed ecotoxicity testing. The methodology for preparing the water for PCA's ecotoxicity testing of fumarated rosin is identical to that used to determine the solubility of this substance. This procedure was adopted in order to ensure that ecotoxicity testing was conducted at the limit of actual water solubility. Accordingly, because the solubility of fumarated rosin will be empirically determined, the same conditions used to prepare these samples will be used to prepare the water samples to be used in conducting the acute fish, daphnia and algae toxicity testing. In addition, as noted in the Test Plan, the effect of both filtering, to further minimize nonspecific physical effects, and of reducing the pH to the lower end of the acceptable range for test organism survival, will also be investigated for changes in toxicological effects. The results of preliminary tests will

be used to select the most appropriate test conditions for the definitive test for each species.

We also acknowledge EPA's suggestion that we consider whether daphnid chronic reproductive testing should be undertaken. However, preliminary data suggest that fumarated rosin has essentially no aquatic toxicity. It is thus unlikely that chronic testing would be needed. In addition, analytical difficulties could preclude chronic testing in any event. Finally, where there is a risk of emulsions forming inherently (as is likely with these substances), flow through testing in not possible and is not recommended in the OECD (2000) Guidance Document 23 (Aquatic Toxicity Testing of Difficult Substances and Mixtures).

EPA also noted that "insufficient information was provided to explain why the testing of fumarated rosin will adequately describe the aquatic toxicity of the maleated rosin adduct given the latter's ability to hydrolyze to the corresponding diacid." As described above, the fact that the fumarated adduct contains a substantial amount of the rosin/maleic anhydride reaction product should effectively address this issue.

Human Health Effects

EPA commented that PCA's choice of fumarated rosin as the test substance was not fully supported in the Test Plan. In particular, the Agency was concerned that the "acylating ability [of maleated rosin] allows it to react with proteins and other biomolecules" which could make this substance more biologically active than the fumarated rosin. However, as explained in greater detail above, testing the fumaric acid adduct will be equivalent to testing the maleic acid adduct as any dissolved anhydride will be readily hydrolyzed to the free maleic acid adduct in an aqueous media. The hypothetical reactivity of the maleic acid adduct (an isomer of the fumaric acid adduct) to proteins should be equivalent to the fumaric acid adduct. Nonetheless, in order to address these concerns, PCA will undertake an additional acute toxicity test (OECD 425, the up-down procedure) on maleated rosin to demonstrate the similarity of toxicity of the two substances.

EPA and PCRM also noted that OECD 401 is being phased out internationally. In our Test Plan, we mistakenly proposed to use this test method on fumarated rosin to meet the HPV SIDS endpoint for acute oral toxicity. Since receiving the comments, we submitted a correction letter on March 19, 2002, stating our intention to perform OECD 425, the up-down procedure instead. We appreciate the opportunity to correct this important point.

EPA and PCRM also suggested that the *in-vitro* dose range-finding protocol be used to set the starting dose for OECD 425 testing. Since it has already been

established that very similar substances within the rosin family are non-toxic following oral exposure, PCA does not believe that this *in-vitro* range-finding procedure is in order. In addition, we note that there are virtually no laboratories capable of performing this procedure as well as no formal validated OECD protocols available.

Amendment to the Test Plan:

Fumarated rosin (CAS # 65997-04-8) will be tested for acute oral toxicity using OECD 425 (up-down procedure) to fulfill this endpoint. In addition, maleated rosin (CAS # 8050-28-0) will also be tested using OECD 425 in order to demonstrate that the proposed testing of fumarated rosin should be representative of the toxicity of maleated rosin. Finally, maleated rosin will be tested to determine the potential to undergo hydrolysis in water (OECD 111).

The revised Table 1 below incorporates the additional acute toxicity test (OECD 425) on maleated rosin, as well as provides a complete picture of the testing to be performed under this Test Plan.

PCA appreciates the comments from EPA and PCRM, as well as the opportunity to respond. We look forward to sharing the data generated pursuant to the Test Plan.

Respectfully submitted,

Walter L. Jones
President & COO

Table 1
Matrix of Available Adequate Data and Proposed Testing on Rosin Adducts and Adduct Salts*

Chemical and CAS #	Required SIDS Endpoints										
	Partition Coef.	**Water Sol.**	**Biodeg.**	**Acute Fish**	**Acute Daph.**	**Acute Algae**	**Acute oral**	**Repeat Dose**	**Gene mutation**	**Chromo-somal aber-ration**	**Repro/ Develop**
65997-04-8, Rosin, fumarated	Test	Test	Adeq.	Test	Test	Test	Test	Test	Test	Test	Test Repro/ Test Develop.
8050-28-0, Rosin, maleated	Test	Test	Test	C	C	C	Test	C	C	C	C
68554-16-5, Rosin, maleated/ fumarated	Test	Test	Test	C	C	C	C	C	C	C	C
68201-59-2, Rosin, fumarated, sodium salt	Test	Test	Test	C	C	C	C	C	C	C	C
68649-83-2, Rosin, fumarated, potassium salt	Test	Test	Test	C	C	C	C	C	C	C	C
85409-27-4, Rosin, maleated, potassium salt	Test	Test	Test	C	C	C	C	C	C	C	C

Adeq. Indicates adequate existing data
Test Indicates proposed testing
C Indicates category read-down from proposed test data on “rosin, fumarated”
***** No testing will be conducted for melting point, boiling point, vapor pressure, hydrolysis (except for maleated rosin), photodegradation and transport and distribution between environmental compartments, as explained in the test plan.